

## **REMARKS**

### Introduction

Claims 114-132 are pending. No amendments are being made at this time. For the record, however, Applicants note their right to pursue in this or a related application inventive subject matter no longer or not yet claimed herein.

Applicants respectfully request reconsideration in view of the following further remarks.

### 35 U.S.C. §102(e) - Novelty

Claims 114-116, 119-126, 128, and 132 stand rejected under 35 USC §102(e) as allegedly anticipated by U.S. patent no. 5,860,957.<sup>1</sup> The '957 patent is said to disclose a series of multiple devices capable of electroporation, each comprising a needle free injector configured to act as a first electrode in contact with a patient's skin and being capable of inducing at least one liquid jet through a nozzle, a second electroporation electrode array comprising ring electrodes, and an electrical connection to a current source configured for creating an electrical potential. The Office further alleges that the '957 patent discloses various sensors for patient and control module programming as well as the use of an ionized solvent for movement of a drug through a created electric field.

Applicants respectfully traverse, as a claim can be anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Despite allegations to the contrary in the Office action, the '957 patent does not disclose an electroporation device that comprises a needle-free injector configured to act as a first electrode. Instead, the '957 patent discloses a combination of separate and distinct drug delivery devices or modes each capable of delivering a drug through the particular device utilizing the particular means of delivery, but none of which itself represents anything even close to Applicants' invention.

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<sup>1</sup> Applicants note that the Office action references the patent used for the 35 U.S.C. §102(e) rejection as U.S. patent no. 5,860,975, when U.S. patent no. 5,860,957 is referenced in Form 892 that accompanied the Office action. Applicants understand that the '957 patent, and not the '975 patent, as the art that was in fact intended to be applied. Accordingly, their response herein addresses the '957 patent. If this understanding is incorrect, Applicants request that the Office clarify the matter in the next action, which in such event should not be made final due to the discrepancy between the body of the Office action and the associated Form 892.

For example, Figure 6 and the corresponding disclosure of the '957 patent relate to an iontophoretic device that does not provide for any injection function. To begin with, and as those in the art are well aware, iontophoresis uses a small, steady electric current to move charged agents through solution or tissue by repulsive electromotive force. Electroporation, on the other hand, uses higher pulsed voltages to generate electric fields that create transient pores in cell membranes through which desired molecules (e.g., drug molecules) can enter. The device in Figure 6 of the '957 patent concerns only iontophoretic electrotransport to drive charged molecules from a pad that has been pressed onto a patient's skin through the skin; there is no injection. In particular, the device of Figure 6 of the '957 patent does not include any needle-free injector, let alone one configured to serve as a first electroporation electrode when positioned in contact with a tissue of a patient. Instead, the "pod aperture 350" of the device of the '957 patent merely contacts the pad, which itself merely sits on top of a patient's skin, such that when the propellant charge is ignited to drive the piston downward, the drug-containing solution in chamber 300 is expelled into the pad 350. To reiterate, there is no needle free injector in the device of Figure 6 of the '957 patent. Indeed, the pod aperture 350 is only an opening, not an electrode. For these reasons, the device of Figure 6 of the '957 patent cannot anticipate Applicants' claimed invention.

The device of Figure 7 of the '957 patent also does not anticipate any of Applicant's claims for the simple reason that the needle-free injector shown in Figure 7 is not an electrode. Put another way, nowhere does the '957 patent teach or suggest a needle free injector that also serves as an as electrode.

Because the '957 patent does not teach or suggest each and every element of Applicants' claimed invention, the cited patent cannot, as a matter of law, anticipate any pending claim. Applicants thus request that this rejection be withdrawn.

### 35 U.S.C. §103(a) – Non-obviousness

Claims 117, 118, and 127 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious in view of a combination of the '957 patent and U.S. patent no. 6,266,560. As discussed above, the '957 patent does not teach or suggest each and every element of Applicants' claimed invention,

and the '560 patent does not compensate for this fundamental deficiency. Because the cited combination also fails to teach or suggest each and every element of the instant claims, no prima facie of obviousness has been made out. Accordingly, this rejection must also be withdrawn.

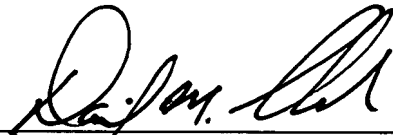
The same result also obtains with respect to fatally flawed 35 U.S.C. § 103(a) rejection premised on the combination of the '957 patent and U.S. patent no. 5,273,525. Put simply, for reasons already discussed the primary reference is defective in that it fails to teach any device having a needle-free injector that is also an electroporation electrode. Like the '560 patent, the '525 patent also fails to compensate for this flaw. As such, this rejection, too, must be withdrawn.

### **CONCLUSION**

Applicants respectfully submit that they has overcome all outstanding objections and rejections and demonstrated the patentability of each of the pending claims. As such, they thus request prompt issuance of a notice of allowance. Of course, if any issue remains that can be dealt with absent a formal action and response thereto, the Examiner is encouraged to telephone the undersigned at his earliest convenience so that the same may be expeditiously resolved.

Dated: 2 Nov. 2007

Respectfully submitted,

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